

a hearing, HHS assesses that laboratory a fee to cover the cost of these activities. Costs are based on the actual resources and time necessary to perform the activities and are not assessed until after the laboratory concedes the existence of deficiencies or an ALJ rules in favor of HHS. HHS revokes the laboratory's certificate for failure to pay the assessed costs. If a complaint investigation results in a complaint being unsubstantiated, or if an HHS adverse action is overturned at the conclusion of the administrative appeals process, the costs of these activities are not imposed upon the laboratory.

[60 FR 20047, Apr. 24, 1995]

§ 493.646 Payment of fees.

(a) Except for CLIA-exempt laboratories, all laboratories are notified in writing by HHS or its designee of the appropriate fee(s) and instructions for submitting the fee(s), including the due date for payment and where to make payment. The appropriate certificate is not issued until the applicable fees have been paid.

(b) For State-exempt laboratories, HHS estimates the cost of conducting validation surveys within the State for a 2-year period. HHS or its designee notifies the State by mail of the appropriate fees, including the due date for payment and the address of the United States Department of Treasury designated commercial bank to which payment must be made. In addition, if complaint investigations are conducted in laboratories within these States and are substantiated, HHS bills the State(s) the costs of the complaint investigations.

[57 FR 7138 and 7213, Feb. 28, 1992, as amended at 60 FR 20048, Apr. 24, 1995]

§ 493.649 Methodology for determining fee amount.

(a) *General rule.* The amount of the fee in each schedule for compliance determination inspections is based on the average hourly rate (which includes the costs to perform the required activities and necessary administration costs) multiplied by the average number of hours required or, if activities are performed by more than one of the entities listed in paragraph (b) of this

section, the sum of the products of the applicable hourly rates multiplied by the average number of hours required by the entity to perform the activity. The fee for issuance of the registration certificate or certificate of compliance is based on the laboratory's scope and volume of testing.

(b) *Determining average hourly rates used in fee schedules.* Three different entities perform activities related to the issuance or reissuance of any certificate. HHS determines the average hourly rates for the activities of each of these entities.

(1) *State survey agencies.* The following costs are included in determining an average hourly rate for the activities performed by State survey agencies:

(i) The costs incurred by the State survey agencies in evaluating personnel qualifications and monitoring each laboratory's participation in an approved proficiency testing program. The cost of onsite inspections and monitoring activities is the hourly rate derived as a result of an annual budget negotiation process with each State. The hourly rate encompasses salary costs (as determined by each State's civil service pay scale) and fringe benefit costs to support the required number of State inspectors, management and direct support staff.

(ii) Travel costs necessary to comply with each State's administrative requirements and other direct costs such as equipment, printing, and supplies. These costs are established based on historical State requirements.

(iii) Indirect costs as negotiated by HHS.

(2) *Federal agencies.* The hourly rate for activities performed by Federal agencies is the most recent average hourly cost to HHS to staff and support a full time equivalent employee. Included in this cost are salary and fringe benefit costs, necessary administrative costs, such as printing, training, postage, express mail, supplies, equipment, computer system and building service charges associated with support services provided by organizational components such as a computer center, and any other oversight activities necessary to support the program.

(3) *HHS contractors.* The hourly rate for activities performed by HHS contractors is the average hourly rate established for contractor assistance based on an independent government cost estimate for the required workload. This rate includes the cost of contractor support to provide proficiency testing programs to laboratories that do not participate in an approved proficiency testing program, provide specialized assistance in the evaluation of laboratory performance in an approved proficiency testing program, perform assessments of cytology testing laboratories, conduct special studies, bill and collect fees, issue certificates, establish accounting, monitoring and reporting systems, and assist with necessary surveyor training.

(c) *Determining number of hours.* The average number of hours used to determine the overall fee in each schedule is HHS's estimate, based on historical experience, of the average time needed by each entity to perform the activities for which it is responsible.

[57 FR 7138 and 7213, Feb. 28, 1992, as amended at 60 FR 20048, Apr. 24, 1995]

Subpart G [Reserved]

Subpart H—Participation in Proficiency Testing for Laboratories Performing Tests of Moderate Complexity (Including the Subcategory), High Complexity, or Any Combination of These Tests

SOURCE: 57 FR 7146, Feb. 28, 1992, unless otherwise noted.

§ 493.801 Condition: Enrollment and testing of samples.

Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538)

prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.

(a) *Standard; Enrollment.* The laboratory must—

(1) Notify HHS of the approved program or programs in which it chooses to participate to meet proficiency testing requirements of this subpart.

(2)(i) Designate the program(s) to be used for each specialty, subspecialty, and analyte or test to determine compliance with this subpart if the laboratory participates in more than one proficiency testing program approved by HCFA; and

(ii) For those tests performed by the laboratory that are not included in subpart I of this part, a laboratory must establish and maintain the accuracy of its testing procedures, in accordance with § 493.1709.

(3) For each specialty, subspecialty and analyte or test, participate in one approved proficiency testing program or programs, for one year before designating a different program and must notify HCFA before any change in designation; and

(4) Authorize the proficiency testing program to release to HHS all data required to—

(i) Determine the laboratory's compliance with this subpart; and

(ii) Make PT results available to the public as required in section 353(f)(3)(F) of the Public Health Service Act.

(b) *Standard; Testing of proficiency testing samples.* The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens.

(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods. The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.